

Appl. No.: 09/934,300

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Amendments to the Specification:

Please amend page 13, lines 10 and 12 as follows:

Example 1: Assay of Bioburden Reduction in a Filtered POE Solution

A 1  
100.7 grams of 3000 MW POE were dissolved in 300 ml of 95% ethanol and 240 ml of the resulting solution were filtered through a 47 mm diameter, 0.2  $\mu\text{m}$  Posidyne® filter under positive pressure. The filtrate was collected in a sterile glass jar and samples were removed, diluted, and filtered through a Milliflex® filter unit for enumeration of bioburden. The samples were plated on sterile R2A agar and incubated for 4 days at 30-35 °C. See, for example, *Official Methods of Analysis of AOAC International* (1995) 17<sup>th</sup> ed., 17.2.05 Official Method 986.32 or 17.3.08 Official Method 983.25. The POE solution contained 151 CFU/ml prior to filtration and 0 CFU/ml after filtration.

Please amend page 13, line 22 as follows:

A 2  
A 2  
A. Assay of Endotoxin Reduction in a Filtered POE/Ethanol Solution

1 ml of purified E. coli LPS endotoxin (Charles Rivers Endosafe®) was added to 435 ml of a 3000 MW POE/ethanol (1:3 w/v) solution, the solution was sampled and then passed through a 47 mm diameter, 0.2  $\mu\text{m}$  Posidyne® filter under positive pressure and collected into a pyrogen-free glass bottle. The filtrate was sampled and both the starting pool and filtrate pool samples were diluted into endotoxin-free water. The endotoxin content of each dilution was determined by a kinetic turbidimetric LAL assay. The spiked starting pool contained 1,009,200 EU and the filtrate contained 346,375 EU. Thus 662,825 EU were removed by the filter.

Please amend page 14, line 1 as follows:

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*B. Assay of Endotoxin Reduction in a Filtered POE/Methanol Solution*

A 3  
Approximately 2 million units of purified E. coli LPS endotoxin was added to 12 ml of a 3000 MW POE/methanol (1:3 w/v) solution, the solution was sampled and 10 ml were passed through a 47 mm diameter, 0.2  $\mu$ m Posidyne® filter under positive pressure and collected into a pyrogen-free glass bottle. The filtrate was sampled and both the starting pool and filtrate pool samples were diluted into endotoxin-free water. The starting pool contained 1,197,490 EU and the filtrate contained 5290 EU. Thus 1,192,200 EU were removed by the filter.

Please amend page 14, line 10 as follows:

*C. Assay of Endotoxin Reduction in a Filtered POE/Acetonitrile Solution*

A 4  
Approximately 2 million units of purified E. coli LPS endotoxin was added to 12 ml of a 3000 MW POE/acetonitrile (1:3 w/v) solution, the solution was sampled and 10 ml were passed through a 47 mm diameter, 0.2  $\mu$ m Posidyne® filter under positive pressure and collected into a pyrogen-free glass bottle. The filtrate was sampled and both the starting pool and filtrate pool samples were diluted into endotoxin-free water. The starting pool contained 1,095,580 EU and the filtrate contained 273 EU. Thus a reduction of 1,095,307 EU was achieved by the filter.

Please amend page 15, line 22 as follows:

*B. Preparation of PHP with a Filtered POE/Ethanol Solution*

A 5  
PHP prepared from a filtered POE/EtOH solution is manufactured as described above with the following modifications. 1953 g POE was dissolved in 6 liters of 95% ethanol, warmed to 40 °C in a stainless steel, pressure rated vessel, with stirring over 20 minutes. The solution was then filtered under pressure (30 PSIG) through an attached Posidyne® 0.2  $\mu$ m capsule filter into a 100 liter chemical modification vessel containing pyridoxylated hemoglobin. The solution in the reactor was stirred during the addition of the filtered POE.